TI SUMMARY SHEET

TRANSPARENCY INTERNATIONAL

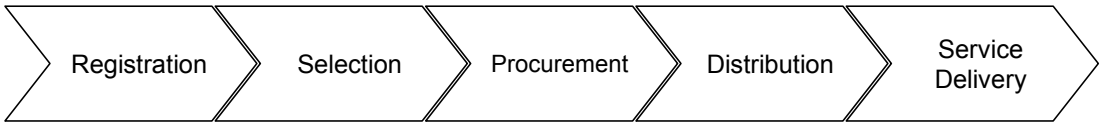
Summary sheet: Corruption in the pharmaceutical sector[1]

The pharmaceutical industry performs a vital service in discovering and developing effective drugs that have saved or improved the quality of many people's lives. Worldwide consumption of drugs is massive and increasing. The industry is very profitable: global sales for the pharmaceutical industry for 2004 were US$ 550 billion, with the largest pharmaceutical companies posting profits of upwards of US$ 10 billion.[2] Companies invest billions in researching and developing new drugs, and typically even greater sums marketing and advertising their most successful products. For the pharmaceutical industry, medical need is combined with the likelihood of a reasonable return on investment.

The tension between public interest and profitability has not always been resolved to the benefit of the general public, with potentially negative consequences for patients that include the inappropriate or excessive use of medicines. Another consequence, and one that exists despite international aid and a plethora of programmes devoted to improving pharmaceutical access, is a morally worrying 'drug gap' between those who can pay for expensive drugs and those who cannot. The World Health Organisation estimates that one-third of the world's population lacks access to essential medicines. Moreover, pharmaceutical expenditures constitute anywhere from 50 to 90 per cent of total individual out-of-pocket expenditures on health in the developing world. Corruption in the pharmaceutical industry exacerbates these problems. While corruption affects the entire population, it is typically the poor who are most susceptible when officials hoard drugs, or waste resources on the wrong kind of medicines.

Corruption in the pharmaceutical supply chain can take many forms: products can be diverted or stolen at various points in the distribution system; officials may demand 'fees' for approving products or facilities, for clearing customs procedures, or for setting prices; violations of industry marketing code practices may distort medical professionals' prescribing practices; demand for favours may be placed on suppliers as a condition for prescribing medicines; and counterfeit or other forms of sub-standard medicines may be allowed to circulate. The pharmaceutical system is technically complex, so each of the five core decision points of the chain – registration, selection, procurement, distribution and service delivery – need to have solid institutional checks and balances in place.

Figure 1: Key processes in the selection and delivery of pharmaceutical products



Registration	Selection	Procurement	Distribution	Service Delivery
• Efficacy • Labeling • Marketing • Use • Warnings • Full registration • Reevaluation of older drugs	• Determine budget • Assess morbidity profile • Determine drug needs to fit morbidity profile • Cost/benefit analysis of drugs • Consistency with WHO criteria	• Determine model of supply/ • distribution • Reconcile needs and resources • Develop criteria for tender • Issue tender • Evaluate bids • Award supplier • Determine contract terms • Monitor order • Make payment • Quality assurance	• Receive and check drugs with order • Ensure appropriate transportation and delivery to health facilities • Appropriate storage • Good inventory control of drugs • Demand monitoring	• Consultation with health professional • In-patient care • Dispensing of pharmaceuticals • Adverse drug reaction monitoring • Patient compliance with prescription

Conflicts of interest between pharmaceutical companies, regulators and doctors

Heavy government regulation in the pharmaceutical chain – while essential to safeguard the population against sub-standard drugs and unfairly priced goods – makes this sector particularly prone to corruption. If regulators are subject to pressure from commercial groups, health objectives can be compromised. Another risk factor is the fact that health needs are unpredictable: governments are unable to plan effectively for future medical need, which diminishes their power to resist offers of medicines at inflated prices or in excessive quantities and to detect corruption in such transactions.

A recent example of the factors in play is provided by the scandal associated with Cox-2 inhibitors Vioxx and Bextra. From an anti-corruption perspective, concerns associated with the drugs – which promised arthritis sufferers pain relief without stomach complications, but were found to double the risk of heart attacks and strokes after 18 months' use – arise because of the composition of the US Food and Drug Administration's advisory panel responsible for assessing whether the drugs should be removed from the market. The panel voted to keep the drugs on the market. It was later learned that 10 members of the 32-person panel had financial ties to the companies that manufactured the drugs, Merck and Pfizer, and that if these conflicted panel members had not voted, the recommendation would have been not to allow either on the market. Both drugs have since been removed from the market. Merck currently faces 9,200 lawsuits over Vioxx.

Wide information asymmetries that exist between patient and physician can also attract opportunities for corruption: patients trust their doctor to prescribe the most effective drug for their condition, but the doctor's decision as to which drugs to prescribe may be influenced by pressure from pharmaceutical companies.

Physicians may feel indebted to drugs representatives, who employ them as paid consultants and members of their advisory boards. In recent years, the pharmaceutical, device and biotechnology industries have spent some US $ 16 billion annually in the United States on marketing to physicians; US $13, 000 a year per doctor, according to the Institute on Medicine as a Profession. The sums involved range from lifestyle changing payments to consultants, to small amounts in trinkets, free meals and trips.

How to tackle conflicts of interest: what physicians should do

The best hope for improving physician behaviour is a combination of the following:

- reasonable and well-publicised standards on how to avoid conflicts of interest between physicians and the pharmaceutical industry, including strict prohibitions on marketing by physicians of drugs or devices in which they have a financial interest, and on participation in company-sponsored speakers' bureaus;
- continuing education about the standards and their foundations, beginning in medical school and continuing at all other levels;
- peer pressure from colleagues and medical associations, including a requirement that clinical practice guideline committees and advisory panels contain a minority of individuals with financial conflicts of interest and that positions of journal editors, officers of major professional organisations and leaders of medical centres and academic institutions be preserved only for individuals without conflicts;
- stricter government regulation of industry involvement in medical research and practice;
- full disclosure of relevant financial conflicts on an easily searchable web site;
- disciplinary action for egregious breaches of such standards.

Counterfeit medicines

Counterfeiting of medicines brings high returns with relatively low risks when compared to narcotics or gun trafficking. The result for the user of fake medicines can be prolonged illness, organ damage or death. The WHO estimates that the global market in fake and sub-standard drugs is worth US $32 billion, or around a quarter of all drugs used in developing countries.[3] In China alone, an estimated 192,000 people died last year because of fake drugs. Corruption and conflicts of interest are the driving forces behind poor regulation, which encourages drug counterfeiting. In addition, inadequate drug control laws or discriminatory legislation by exporting countries compromises the quality of drugs on the international market. Other contributing factors are ignorance and poor public awareness of the problem; a chaotic drug distribution system; misleading advertising; excess demand for drugs; inadequate funding of regulatory authorities; lack of cooperation between government agencies; false declarations by importers; and the sophistication of clandestine drug manufacturing. Organisations, such as the National Agency for Food and Drug Administration (NAFDAC) in Nigeria have achieved some success in combating the problem, by lobbying for a strong regulatory environment, while encouraging intolerance of counterfeit drugs through public awareness campaigns. Efforts to tackle counterfeit medicines must be redoubled, however, so that the producers of such drugs and the public officials who collude with them are prosecuted and duly sanctioned.

Recommendations for the pharmaceutical industry

Given the potential for undue influence on prescribing behaviour, global standards have been developed and a number of professional bodies, including pharmaceutical industry associations, have enacted codes of conduct that detail best practice in minimising corruption. These include the strengthening of marketing and promotion codes, and greater transparency and access to information on clinical trials. But inappropriate drugs promotion is still a problem in both developing and developed countries. The drugs industry and other stakeholders need to intensify efforts to prevent abuses in the following way:

- pushing for the harmonised regulation of pharmaceutical products on the international market;
- introducing whistleblower mechanisms and protection;
- developing a public database listing the protocols and results of all clinical drug trials;
- implementing conflict of interest rules that disqualify individuals or groups with an interest in the manufacturer from participating in clinical drug trials;
- obligatory reporting of all financial contributions made to medical research units from pharmaceutical companies;
- prohibiting all gifts from the pharmaceutical industry, even items that might be considered useful in a doctor's practice or education;
- prohibiting consultations with the drugs industry for anything except scientific matters so that health policy is not unduly influenced by the financial concerns of pharmaceutical companies; and
- signing up to and implementing the Business Principles for Countering Bribery, through which enterprises prohibit bribery in any form, whether direct or indirect, and commit to the implementation of a programme to counter bribery.[4]

The role of civil society organisations

Civil society organisations can play a key role in promoting the rigorous application of best practices and codes of conduct on the part of the pharmaceutical industry, members of the medical profession and governments. Not only can expert pressure groups be highly instrumental in investigations of malpractice, but they play a vital role by representing ordinary individuals who may lack information about their entitlements or health standards, and may fear losing access to services if they file public complaints. For example, the Guatemalan chapter of Transparency International (TI Guatemala) monitored drugs procurement in mid-2005, on the invitation of the government. At the time, a legal dispute between generic and brand name distributors of medicines had caused severe shortages. Through the monitoring process, TI Guatemala uncovered significant bias on the part of the governmental body responsible for checking compliance with quality controls. Certain bidders were required to provide additional technical information at short notice, in contrast to a favoured group of companies. The requests for more information effectively excluded providers of generic drugs. The potentially damaging effects of this high level of discretion by the governmental adjudication body were magnified by the lack of a public health policy, which meant that the quantities purchased could also be manipulated. The recommendations of the monitoring exercise were used to lobby successfully for a public health policy determining the amount of medicines to be purchased each year in Guatemala.

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[1] This brief is based on the papers by Jillian Clare Cohen, 'Pharmaceuticals and corruption: a risk assessment'; Jerome P. Kassirer, 'The corrupting influence of money in medicine'; John R. Williams, 'Fighting corruption: the role of the medical profession; and Dora Akunyili, 'The fight against counterfeit drugs in Nigeria', published in Transparency International's *Global Corruption Report 2006* (London: Pluto Press, 2006).

[2] The US NGO Center for Public Integrity as part of its programme 'Pushing prescriptions' maintains a website with information about lobbying and marketing activities of major pharmaceutical companies, see www.publicintegrity.org/rx/default.aspx

[3] 'Fake and Counterfeit Drugs', WHO fact sheet 275, November 2003.

[4] The Business Principles for Countering Bribery are an initiative facilitated by Transparency International and Social Accountability International, aiming to provide a practical tool to which companies can look for a comprehensive reference to good practice in countering bribery. For more information see: www.transparency.org/building_coalitions/private_sector/business_principles.html#countering